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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,707	07/06/2001	Roger E. Darois	D0188/7126	4890

7590

01/09/2004

Jason M. Honeyman
Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
6000 Atlantic Avenue
Boston, MA 02210

EXAMINER

BONDERER, DAVID A

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 01/09/2004

(6)

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,707

Applicant(s)

DAROIS ET AL.

Examiner

D. Austin Bonderer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46,50-66 and 68-71 is/are rejected.
- 7) ☒ Claim(s) 47-49 and 67 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 71 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 71 recites the limitation "the margin section" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 46, 50, 53, 54, 56, 59, 60, 62, 65, 66, 68 and 71 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mulhauser et al.

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Mulhauser discloses a mesh with an impenetrable layer that covers the side and edge comprising:

- A polypropylene mesh layer 12;
- A barrier layer (fig. 3h) that inhibits growth on the interior body section of the mesh fabric;
- A edge barrier layer (fig 3h); and
- A method of implanting the prosthesis.

A silicone elastomer layer forms the barrier layer. By all accounts the layer is smooth and not deliberately textured. "Things clearly shown in the reference patent drawing qualify as prior art features, even though unexplained by the specification." *In Re Mraz*, 173 USPQ 25 (CCPA 1972). The Eldridge reference 5,766,246 describes silicone elastomer as a suitable barrier, equating it to ePTFE having a fine pore size that discourages tissue ingrowth and viscera adhesion. Also inhibit means in *Biology*. To decrease, limit, or block the action or function of (an enzyme or organ, for example).¹ The silicone elastomer of Mulhauser performs that function or it would have been obvious to one of ordinary skill in the art to make it smooth in order to aid and prevent harming surrounding tissue during placement.

4. Claims 51, 52, 55, 57, 58, 61, 63, 64, 69, and 70 rejected under 35 U.S.C. 103(a) as being unpatentable over Mulhauser in view of Eldridge.

¹ *The American Heritage® Dictionary of the English Language, Third Edition* copyright © 1992 by Houghton Mifflin Company. Electronic version licensed from INSO Corporation; further reproduction and distribution restricted in accordance with the Copyright Law of the United States. All rights reserved.

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- Mulhauser teaches the use of a continuous connection between the mesh and the barrier.

This is considered to be a continuous stitching.

Mulhauser lacks the use of ePTFE for the barrier layer. Eldridge teaches the use of ePTFE for the barrier layer. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide Mulhauser with the ePTFE as taught by Eldridge since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Allowable Subject Matter

- 5. Claims 47, 48, 49 and 67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

- 4. Applicant's arguments filed 2-23-03 have been fully considered but they are not persuasive. As mentioned in the rejection the drawings show that the barrier to be smooth. The examiner is holding it to be so or obvious to make it so. In the injection molding process it is easier to remove the barrier from the mold if it is smooth. It is therefore adventitious to one of ordinary skill in the art to adhere to the drawings of Mulhauser and make it smooth.

- 5. Also the applicant is claiming stitches. Wouldn't these holes provided for areas for molecular tissue growth? However on the whole, the layer inhibits growth.

- 6. Also the applicant is arguing that it inhibits growth on a micro-level. This is not claimed. Further inhibiting growth just means "To decrease, limit, or block the action or function of (an enzyme or

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organt, for example).² There is no argument presented before the examiner that the barrier layer of Mulhauser doesn't perform this function.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Austin Bonderer whose telephone number is 703.306.5911. The examiner can normally be reached on Monday- Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on 703.308.2582. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0873.

dab


PEDRO PHILOGENE
PRIMARY EXAMINER

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